2009
Annual Report
January - December 2009
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<td>Abbott Laboratories South Africa (Pty) Ltd</td>
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<td>Adcock Ingram Healthcare (Pty) Ltd</td>
<td>iNova Pharmaceuticals (Pty) Ltd</td>
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<td>AHN Pharma (Pty) Ltd</td>
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The Pharmaceutical Industry Association of South Africa (PIASA) is a trade association of companies involved in the manufacture and marketing of prescription medicines in South Africa. The association promotes and safeguards the interests of its members vis-à-vis government, business and other professional organisations. PIASA focuses on the transformation and demands of the local healthcare environment.

Membership is voluntary and includes a broad representation of foreign multinational pharmaceutical companies and local companies. PIASA’s members in 2009 supplied approximately 40% of the total pharmaceutical market in South Africa.

The members of PIASA aim to bring quality medicines to the South African market. PIASA companies are important members of the South African business community, marketing medicines, including both innovative and generic medicines, to the health professions. In addition to promoting and safeguarding the interests of members, PIASA provides a service to the public as well as the general medical and healthcare community.

**Mission**

To sustain a favourable environment for the continued development of the pharmaceutical industry in South Africa as it strives to increase access to quality medicines, with the ultimate aim of saving lives and improving the quality of life for all South Africans.

**Values**

Members of PIASA subscribe to the following values:

- Respect for intellectual property rights
- Commitment to good corporate governance
- Commitment to the Code of Marketing Practice
- Adherence to best practice in manufacturing, clinical research, distribution and regulatory affairs

**Profile**

Trade organisation with voluntary membership.

Members are drawn from research-based multinational pharmaceutical companies operating in South Africa and local manufacturers of pharmaceuticals.

22 members at December 2009.

PIASA represents South Africa internationally as a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).
Vision
Promoting the image, views and interests of the industry to a broad range of audiences.

Carrying out business in such a way as to support the strategic national health priorities of government.

Partnering with government in determining the best avenue for improving access to quality medicines for all South Africans.

Maintaining close and regular contact with political opinion leaders, government bodies and stakeholders in order to create a favourable political and economic environment for our members.

Presenting a unified industry approach to the broader challenges of healthcare in South Africa.

Working closely with government and other bodies in the development of legislation relevant to the pharmaceutical industry - in an ethical and responsible manner.

Working towards an appropriate regulatory environment and providing technical advice and guidance.

Objectives
- Represent PIASA members and the industry in dealing with Government with a view to providing constructive input and influencing legislation and policy developments affecting the health sector for the ultimate benefit of patients.

- Liaise with funders of medical services in the private sector to address issues that impact the industry.

- Work with the medicines regulatory authority (MCC) in shaping strategic issues of a regulatory nature relating to clinical trials and the registration of medicines.

- Be instrumental in assisting members with the implementation of Broad-Based Black Economic Empowerment.

- Keep members abreast of legal, scientific, technical, economic and trade issues that impact them.

- Provide relevant information and advice to members as appropriate.

- Promote, support and oversee industry guidelines on the ethical marketing of medicines to ensure compliance with the PIASA and IFPMA Codes of Marketing Practice.
The PIASA Executive Council is democratically elected annually and leads the association in decision-making, providing strategic leadership and determining policy. Elected from Exco is the Management Council which is responsible for financial issues and administration.

The Science and Technology (SciTech) and Marketing Committees, two expert committees, report to the Executive Council. During 2009 six additional ad hoc committees dealt with the main issues of importance to industry: Government Affairs and Policy, Transformation, Health Outcomes, Intellectual Property, Local Manufacturing, Export and Communications.

The numerous activities of PIASA are supported by a secretariat under the leadership of the Chief Operating Officer, Vicki Ehrich, who reports to the Executive Council.
PIASA Committee Structure

The work of the executive team is complemented by the efforts of the wider membership through various committees and the PIASA Secretariat. A great deal of time and resources is spent on the most pressing industry issues and priority committees are formed to deal with these. Exco offers strategic direction and leadership to the association.

Executive Council Members

The 2009/2010 PIASA Executive Council was elected at the Annual General Meeting held on 5 August 2009. The following persons were elected to the 2009/10 Executive Council: Jonathan Louw (Adcock Ingram), Gunil Goolab (AstraZeneca), Peter Lyons (Abbott), Richard de Chastelain (Bayer HealthCare), Kobus Venter (Janssen-Cilag), Eric Reurts (Novo Nordisk), Ashley Pearce (Schering-Plough), Ismet Amod (Sekunjalo/ Bioclones) and Jay Hooghuis (Wyeth). Deon Vos (outgoing President – August) resigned from Exco in October 2009 when he was transferred to Philadelphia by Merck. Sudier Ramparsad (Bristol-Myers Squibb) was co-opted to fill Deon’s position on Exco. Pierre Bosch (Alcon) replaced Jay Hooghuis (Wyeth) on the Executive Council following the merger between Wyeth and Pfizer.

Management Council

PIASA’s Management Council is responsible for financial and administrative matters. The Management Council was elected by the Executive Council on 5 August 2009. Jonathan Louw (Adcock Ingram) was elected President. Ashley Pearce (Schering-Plough), Eric Reurts (Novo Nordisk) and Jay Hooghuis (Wyeth) were elected as Vice-Presidents. Peter Lyons (Abbott Laboratories) took over from Jay Hooghuis in October, following the takeover of Wyeth by Pfizer.

Committees to the Exco

PIASA’s priority committees are structured to address the most pressing needs of industry and are reviewed annually. Standing committees, SciTech and Marketing, continue as core to the organisations’s activities. Full reports on these committee activities are available from page 11 in this report.

Government Affairs & Policy - The primary task of the Government Affairs & Policy Committee is to deal with public policy affecting the industry. Issues such as pricing of medicines, National Health Insurance and benchmarking are addressed by this Committee.

Transformation - The Transformation Committee leads and supports members in the implementation of Broad-based Black Economic Empowerment.

Intellectual Property - This group is responsible for safe-guarding members’ interest in terms of intellectual property matters, which are key to this industry.

Health Outcomes / Heat - The Health Outcomes Committee addresses issues affecting the funding of and access to medicines in the private sector with a focus on the interests of patients.

Local Manufacture - This Committee promotes the value of local manufacture of medicines go South Africa and addresses regulatory issues affecting these interests.
**Communications** - Issues relating to the image of the industry and PIASA are the main focus of the Communications Committee. This group aims to communicate the value of both medicines and local industry investment to a broad audience.

**Export** - The Export group was established in September 2009 to deal with members’ interest relating exports.

**Science and Technology (SciTech)**

SciTech acts in the interests of members on all scientific, regulatory, clinical and technical matters. The activities of SciTech and its various sub-committees are reviewed annually in order to address the most pressing issues and add more value to member companies in a proactive manner.

**Marketing Committee**

The Marketing Committee is dedicated to the development of a regulated South African Code of Marketing Practice and oversees the adherence to these principles by the membership.

As a member of the International Federation of Pharmaceutical Manufacturers and Associations, the committee upholds the standards of the IFPMA Code of Marketing Practice.

**2009 PIASA Structure**

- **Management Council (elected)** – financial & administrative matters
- **Executive Council (elected)** – strategic direction & leadership
- **Strategic Committees to the Exco**

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[Diagram of PIASA Structure]

- **Management Council**
  - **Executive Council**
    - **Marketing Committee**
      - **Science & Technology Committee (SciTech)**
        - Kobus Venter
      - **NHI Group**
        - Eric Reurts
      - **Government Affairs/Policy**
        - Jonathan Louw
      - **Transformation**
        - Guni Goolab
      - **Health Outcomes**
        - Peter Lyons
      - **Communication**
        - Richard de Chastelain
      - **Export**
        - Pierre Bosch
      - **Intellectual Property**
        - Peter Lyons
    - **Local Manufacture**
      - Kuben Pillay
    - **Supported by the Secretariat**
PIASA Executive Council

Elected August 2009

Jonathan Louw
Adcock Ingram
Management Council Member
President

Eric Reurts
Novo Nordisk
Management Council Member
Vice-President

Ashley Pearce
Schering-Plough
Management Council Member
Vice-President

Peter Lyons
Abbott Laboratories
Management Council Member
Vice-President (from Oct)

Guni Goolab
AstraZeneca

Richard de Chastelain
Bayer Schering Pharma

Jay Hooghuis
Wyeth
Management Council Member and Vice-President until Sept 2009

Pierre Bosch
Alcon Laboratories
From October 2009

Kobus Venter
Janssen-Cilag

Ismet Amod
Bioclones

Sudier Ramparsad
Bristol-Myers Squibb
Co-opted member From October 2009

Deon Vos
Merck
President until August 2009
Exco Member until October 2009

The functioning of the Executive Council was supported by the COO, Vicki Ehrich
and the Head: Scientific & Regulatory Affairs, Kirti Narasi

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Introduction and Summary

Dealings with Department of health were complicated by the changes in leadership which included the departure of the Honourable Minister of Health, Ms. Barbara Hogan (appointed in October 2008) and the appointment of Dr. Aaron Motsoaledi on 11 May 2009. The contract of the Director General of Health, Mr. Thami Mseleku, was terminated at the end of September 2009.

During the year under review much attention was given to National Health Insurance (NHI), which remained a priority issue for Government. Key issues facing the industry, being the National Health Insurance and Drug Policy, compact offerings and benchmarking of medicines, pricing of medicines and Industrial Policy was addressed.

Priority Issues

Key strategic areas addressed by the PIASA’s committees were: Government Affairs and Policy; Transformation; Healthcare Funding; Communications; Local Manufacturing and Intellectual Property. The standing committees, SciTech and Marketing, continued as core to the organisation’s activities.

A very short synopsis of the most important issues dealt with by the priority and standing committees follows:

Government Affairs and Policy

National Health Insurance – This priority area for government occupied much media space during the year despite the fact that no policy document has yet been published. The Health Department’s Ten Point Plan for 2009 to 2012, was published in March 2009 and included National Health Insurance.

A very successful PTG meeting was convened with international speakers in November 2009. Thereafter PIASA took the initiative to work on a NHI Policy document for pharmaceuticals under an NHI system.
The National Health Insurance Advisory Committee, appointed in September 2009, continues to advise the Honourable Minister of Health. There is no certainty on when a policy paper will be submitted to parliament.

**Annual Price Increases** - The price increase of 13.2% granted by the Department of Health was to be implemented by no later than September 2009. A request for comment on the 2010 increase was published in November 2009. The eventual announcement was made on 17 March 2010 allowing a 7.4% conditional increase. The PTG dealt successfully with DoH on having the conditions attached to the price increase removed in 2010. The PTG further discussed the interpretation and operation of the pricing regulations with Dr Kamy Chetty, then acting D.G. of the DoH, in an attempt to ensure a regular and predictable price increase cycle for the future.

**International Benchmarking** – Since the publication of the draft methodology on international benchmarking of prices in December 2006, numerous submissions, meeting and negotiations have taken place. Despite this the matter remains unresolved and it is uncertain what the intention of the DoH is on the matter. Late in 2009, the PTG was asked to review their position on international benchmarking by the DoH. After due consideration, a submission was made to Dr Anban Pillay on 15 December 2009, stating that the PTG position had not changed.

As an alternative to benchmarking of medicine prices, the concept of a social compact was raised with Ms Barbara Hogan. With the change in leadership, this proposal was not taken forward to the new Ministry.

**Transformation**

PIASA continued to support members in terms of the implementation of B-BBEE, started in 2008. A membership survey indicated that 11 out of 17 members intended to be rated at their financial year end. The Transformation group offered support over the year with the assistance of consultants, Transcend Corporate Advisers and has run two workshops. The way forward is the consolidation of members’ ratings and the creation of a PIASA benchmark. Workshops with a very practical approach will continue in 2010.

**Intellectual Property**

PIASA and IMSA committed to co-operate on relevant intellectual property matters and various meetings were held during the year. IMSA pursued data exclusivity as their priority issue while PIASA were more involved in and committed to patent term restoration. The likelihood of success on either issue was considered to be limited.

**Health Outcomes**

The group focused on issues around funding of and access to medicines and the Consumer Protection Act.

Several workshops were held that focused on these areas, viz. the Consumer Protection Act training session with dti, Medical Schemes workshop where CMS representatives presented on PMBs, trustees and medical scheme governance issues and Dinokeng scenarios, which focused on scenario planning for South Africa.

The group also completed Case Study Project to assess medicine reimbursement issues. The study was outsourced to Benguela Health for confidentiality and competition reasons. 33 cases were collected and analysed. Key findings related to incorrect application of co-payments and deviations from legal framework as set out in Medical Schemes Act.

Several submissions were made to the Council for Medical Schemes on policy documents published for comment. These included:

- Comment on PMB review document
- Managed care accreditation standards
- Fit and proper standards for principal officers and trustees
- Proposed corporate governance guidelines for medical schemes
Exemption from Competition Act - PIASA challenged the Board of Healthcare Funders (BHF) application to the Competition Commission for an exemption from the Competition Act. The application by BHF did not succeed but BHF has asked the Minister to reconsider as this would have severe consequences for their members. This is of huge concern to PIASA. If BHF succeed it will be detrimental to the pharmaceutical industry.

**Local Manufacture**

Local preference for tenders (289-MF) was one of the main issues addressed. With the exception of adjustments to volumes no changes to the requirements were published. Matters relating to local manufacturing incentives and how to stimulate industry investment overall was discussed with Andre Kudlinski from the dti.

**Communications**

Much effort was put into the communications activities with good coverage received. Of major importance was the publishing of an “Overview of Industry” (FinWeek), and PIASA members signing up for Ethical Marketing. Regular advertorial pages were published in the Medical Chronicle covering, amongst other matters, the Marketing Code, Transformation and Medicine Price increases. Advantage was taken of all opportunities for exposure by responding to major issues.

The PIASA website was reconstructed in order to expand the information provided on the site, improve the appearance and to offer easier navigation.

A very successful update and briefing session for PIASA members was held on 6 November 2009.

**SciTech**

**Regulatory** - The group commented on various technical guidelines published by the Medicines Control Council and submissions made to the Medical Products Technical Task Team outlined regulatory issues experienced with recommendations for improvement. Submissions, with proposals, were also made to the MCC on: SR-PINs, PILs, proprietary names and recall of medicines.

Following changes in legislation in Namibia which require registration details on medicine packs PIASA brokered a very successful meeting between the Namibian and SA Registrar resulting in approval granted by the MCC to add this on the South African packaging.

The backlog in medicine registration was pursued and the MCC was requested to treat the clearing of the backlog as Phase One.

The amended Act on medicines control was published and new regulations which will give effect to the amendments are pending. Current regulations and guidelines were reviewed in anticipation of the pending regulations.

**Clinical** - SARS was successfully challenged on the exclusion of clinical trials from the Draft Interpretation Note on Tax Incentives for R&D activities. A very successful Clinical Workshop was held in August where questions was put to Dr Misra of the MCC, future clinical trials and the electronic document management submission were discussed.

**Pharmacovigilance** – The ADR Guidelines was updated to bring it in line with international standards. This revised ADR Guidelines was submitted to the MCC. A submission was also made to the NMRC (Namibia) on their draft pharmacovigilance guideline and a comprehensive database has been established outlining reporting requirements for African countries which members can use as a reference guide for reporting. Audit packs of the reporting guidelines for African countries were compiled and distributed to members for audit purposes.

**Quality Management** - Submissions were made to the MCC on revised GMP guidelines and stability guidelines. The group initiated a Quality Risk Management project, to assist and support member companies in their preparation for risk management audits. Significant progress has been made on this project, which is being continued in 2010.
A successful workshop focusing on Counterfeit Medicines was held at PIASA on 17 July 2009, included speakers such as Griffith Molewa (DoH) and Johan Bothma (PSSA). The workshop was attended by members of PIASA, IMSA, wholesalers as well companies responsible for the destruction of medicines.

Marketing

Over 60 representatives of the pharmaceutical industry attended a marketing code workshop hosted by PIASA (Pharmaceutical Industry Association of South Africa) and attended by DoH representative, Dr Joey Gouws. Mr Richard Bergstrom, Director General of LIF in Sweden (also the advisor to the World Health Organisation) spoke on the IFPMA Code of Marketing Practices.

PIASA continued to participate actively in the Marketing Code Steering Committee. Progress was made during 2009 in finalizing the Code content and agreeing a structure of enforcement with DoH. MCC accepted the Code content proposed by the Marketing Code Steering Committee and indicated their commitment to finalizing and publishing the Code as soon as possible.

PIASA continue to participate in global forums such as the IFPMA to create a developing country focus for input into policy development. While the IFPMA Code must take into account the diversity of all the markets it serves, our Code must necessarily be SA-centric.”

PIASA participated in the Global Code Compliance Survey which focused on comparing requirements of Codes around the world using a scoring system with a maximum score of 34. South Africa scored 32, compared to USA with 24, UK on par with 32.

Membership

Resignations – Due to the agreement with Aspen Pharmacare, GlaxoSmithKline and Stiefel resigned in October 2009. Following the merger with Pfizer, Wyeth resigned in October. These resignations will be effective in January 2010. Boehringer Ingelheim resigned December 2009.

Industry consolidation – During 2009, the matter of consolidation with IMSA remained unresolved. A research project on the part of the two associations in 2010, showed that there was not an immediate agreement on the benefits of consolidation.

Member subscription fees - At the Annual General Meeting held in August 2009, it was agreed that there would be no increase in subscription fees for 2010.

Honorary Life Membership

Maureen Kirkman was awarded Honorary Life Membership of PIASA for her enormous contribution to PIASA and to the pharmaceutical industry. She has spent almost her entire working life in the pharmaceutical industry, the last 11 years as Head: Scientific and Regulatory Affairs at PIASA.

Thanks

PIASA once again, thank members of the Executive Council, the Management Council and the various Committees to the Exco for their commitment, support and dedication to the affairs of PIASA. A special word of appreciation is extended to those member companies and their employees who participated so willingly in the activities of the Association during the year.

We also thank our staff at the PIASA Secretariat for another year of hard work.

Details on the PIASA finances can be found under the Financial Report on page 24.
Committees to the Exco

Government Affairs and Policy

The Majority of the work on pricing matters was done though the Pharmaceutical Task Group (PTG), a grouping associations involved in pharmaceutical matters i.e. Innovative Medicines of South Africa (IMSA), National Association of Pharmaceutical Manufacturers (NAPM), Pharmaceuticals made in South Africa (PHARMISA), PIASA and the Self Medication Association of South Africa (SMASA). This grouping of associations represents multinational, generic and self-medication interests.

The PTG made constructive proposals and developed submissions in response to legislative issues, supported by face-to-face presentations when possible. Matters dealt with during the year related mostly to the pricing of medicines and interaction was largely with the Pharmaceutical Economic Evaluations Unit (PEEU).

A new Minister of Health, Dr Aaron Motsoaledi, was appointed on 11 May 2009, replacing Ms. Barbara Hogan.

NHI, Pricing of Medicines, International Benchmarking and Social Compact

The intention to introduce a national health system in South Africa has long been part of the health policy of the country. The ANC published this as item No. 53 of the resolutions of the ANC National Congress held in Polokwane in December 2007.

The Department of Health published their Strategic Priorities under the signature of the then Director General, Mr Thami Mseleku, dated 10 March 2009. National Health Insurance is the second priority of the list of 10 priorities. The plan is for the period 2009 to 2012.

In September 2009 the formation of a National Health Insurance Advisory Committee was announced, to advise the Honourable Minister of Health on the development of an NHI strategy. There are no industry-specific representatives on the advisory committee. Members have been chosen for their expertise and knowledge.

The PTG convened a very successful workshop on NHI on 18 and 19 November 2009. International speakers were invited, a mix from corporate head offices and independent experts.

An output document was developed recording the thoughts and proposals made during the meeting.

From then on there was not agreement within the PTG as to how to progress the NHI issue. IMSA favoured a macro policy approach and PIASA members preferred a specific pharmaceutical policy approach.

PIASA created an ad hoc committee of volunteers, under the leadership of Eric Reurts (Novo Nordisk), to develop a paper on pharmaceuticals within a national health system, in order to be prepared with a PIASA position on the matter.

The paper was based partially on output from the PTG workshop together with extensive research undertaken by the group, which included studies of systems in foreign countries, policy documents, input from members and assistance from the workshop speakers. The document was compiled by a researcher who facilitated the process.

The anchor principles adopted in this document included the support of universal access to quality medicines, the need for a strong and stable local pharmaceutical industry and a mandatory funding system for medicines.
Pricing of Medicines

The work on pricing was undertaken largely within the Pharmaceutical task Group (PTG).

Annual increases in the SEP

Following a call for comment on the annual review of the single exit price of medicines and scheduled substances, published in Government Gazette no 31327 on 11 August 2008, two submissions were made through the PTG. This was followed by the announcement of an increase of 13.2%, which had to be implemented by no later than 1 Sept 2009 up to a maximum amount of 13.2% of the single exit price that prevailed on 1 Dec 2008.

A further notice, requesting comment on the price increase for 2010, was published in Government Gazette 32684 on 6 November 2009. In a meeting with Dr Karmani Chetty (acting D.G, DoH) implications for the interpretation and operation of the pricing regulations were discussed, with the objective of ensuring the effective and efficient price increase implementation in 2010 and beyond.

International Benchmarking

Since the publication of the draft methodology on international benchmarking of prices in December 2006, numerous meetings, submissions, and negotiations took place. Legal advice was sought throughout the process. The matter of international benchmarking remains unresolved.

Late in 2009, the PTG was asked by Dr Anban Pillay, Cluster Manager, Financial Planning and Health Economics, to review their position on international benchmarking and to advise him of the current position. After due consideration, a submission was made to Dr Pillay on 15th December 2009, in summary, stating that the PTG position had not changed.

In previous submissions, objections were raised to the application of the ‘lowest price’ methodology, rather than the average. Concerns relating to the treatment of the exchange rate were raised and the understanding that benchmarking should be a ‘once-off’ process was emphasised.

As an alternative to benchmarking of medicines prices, IMSA and PIASA proposed a social compact, whereby pharmaceutical companies would make a contribution to a Public Sector Capacity Building Fund, based on an agreed percentage of sales.

It was proposed that such a contribution would make a bigger impact on access to medicines than international benchmarking.

Although PTG negotiated with Ms Barbara Hogan to consider such an offering in place of International Benchmarking of private sector medicine prices, the situation had to be re-assessed with the change in leadership of the Health Ministry. The proposal was not carried forward to the new ministry although officials were aware of the proposal.

Within the PTG, an alternative philanthropic proposal was developed under the leadership of Dr Guni Goolab. The objective of this proposal was to make a positive impact on the distribution of medicines within the state sector, by auditing the infrastructure and skills at a sample of dispensaries and upgrading these selected sites.

The plan included inventory management systems; minimum stock levels; Standard Operating Procedures (SOP’s) for ordering, receiving, storage and disposal of medicines; a reliable delivery system for the distribution of stock and improved communication between the depots and districts.

Industrial Policy

Industrial Policy Action Plan (IPAP)

The adoption of a National Industrial Policy Framework with a supporting Industrial Policy Action Plan (IPAP) was adopted by Cabinet in June 2007. This focused mostly on the supply of ARVs to the state.

On 19 February 2010, the Minister of Trade and Industry, Mr Rob Davies, tabled before parliament a new Industrial Policy Action Plan, which seeks to give preference to local manufacturers. The plan allows, for example, local bidders to match or better the bids of foreign-based competitors for supply of medicines to the state.

In September 2008, dti requested comment on draft tax incentives for industry, to which PIASA responded. The final plan relating to these tax incentives was published in January 2009.
Summary of important dates:

- 24 Dec 2008: Determination of maximum increase in the single exit price – Government Gazette 31735
- 11 Aug 2008: Call for comment on annual single exit price – Government Gazette 31327
- 22 May 2009: Revised procedure for updating single exit prices – Government Gazette 32245
- June 2009: DG presentation to Portfolio Committee – Ten strategy priorities for period ending 2012.
- 6 Nov 2009: Annual review of single exit price – Government Gazette 32684
- 15 Dec 2009: Submission by the PTG on position on International Benchmarking

PIASA representatives to the PTG: Jonathan Louw (Adcock Ingram), Ashley Pearce (Schering-Plough), Peter Lyons (Abbott), and Eric Reurts (Novo Nordisk).

**Ad Hoc Committee Members (August 2009 – August 2010):** Eric Reurts (Novo Nordisk), Sudler Ramparsad (Bristol-Myers Squibb), Alan Rusch (Boehringer Ingelheim), Wolfgang Gotz (Boehringer Ingelheim), Barry Wren (Covidien), Shelley Horner (Merck Serono), Ashley Pearce (Schering-Plough), Gerdi Strydom (Wyeth), Vicki Ehrich (PIASA), Reg Magennis (Elixir Health), Peter Lyons (Abbott Laboratories), Glen Watkins (Bayer Schering Pharma), Tom Molokoane (Abbott), Mohammed Majid (AstraZeneca), Godwin Jacob (Merck Serono), Hennie Duvenhage (Novo Nordisk), Dirk van Niekirk (Boehringer Ingelheim), Ignatius Viljoen (Boehringer Ingelheim).

**Committee Members (August 2009 – August 2010):** Peter Lyons (Abbott Laboratories) – Chairperson, Jay Hooghuis (Wyeth), Kobus Venter (Janssen-Cilag) and Vicki Ehrich (PIASA).

**Committee Members (August 2008 – August 2009):** Peter Lyons (Abbott Laboratories) – Chairperson, Jay Hooghuis (Wyeth), Kobus Venter (Janssen-Cilag) and Vicki Ehrich (PIASA).

**Intellectual Property**

The focus of the Intellectual Property Committee, chaired by Peter Lyons (Abbott Laboratories), centered on patent term restoration and data exclusivity.

PIASA and IMSA committed to co-operate on relevant intellectual property matters and various meetings were held during the year.

While IMSA was committed to pursuing data exclusivity as their priority issue PIASA had been more involved in and committed to patent term restoration.

PIASA aligned their approach with bodies such as the IFPMA (International Federation of Pharmaceutical Manufacturer Associations).

Discussions on the Intellectual Property issues were held during the year with Mandisa Hela, registrar of the MCC and MacDonald Netshitenzhe of the dti.

At a meeting attended by PhRMA representatives (Pharmaceutical Research and Manufacturers of America), Mandisa Hela suggested that intellectual property, a policy issue, should be addressed at ministerial level. She recommended that a policy submission be made to the Ministers of Health and dti.
The Transformation Committee, chaired by Guni Goolab (AstraZeneca) assisted members with the transformation process through: guidance, the appointment of a consultant that can be used; workshops and training.

**Assistance and Workshops**

PIASA signed an agreement with Robin Woolley to be an advisor and consultant for PIASA to provide: feedback on industry progress; telephonic support to all members, BB BEE workshops and a BEE toolkit which included a workbook and electronic resources aimed at the needs of the pharmaceutical industry.

The two transformation workshops held during 2009 (26 May and 14 October) added much value in assisting members with the transformation process. Training was given on detailed preparation of all 7 elements for BB BEE audits and collecting supporting evidence with feedback on the B-BBEE status amongst the member base.

Furthermore members were given guidance on practical actions companies should be doing in the last 2 months of the year to ensure transformation and BEE initiatives are well positioned at year end.

A benchmarking survey with the title: “2010 Roadmap”, will be conducted in 2010 and the results from this survey will be included in the three workshops planned for 2010. The objective of the workshops are to help members to formalise themselves with the process of employment equity and skills, and transformation within the companies.

**Baseline Study**

The baseline study around BEE pillars conducted amongst PIASA members reflected that 11 members indicated a readiness and plan to be assessed at the end of the 2009 financial year.

The study was intended to establish the progress made by members in the transformation process and to understand their needs, in order to plan how best to support the membership with BEE implementation.

**Support Programme**

The support programme was started to assist members with the implementation of BEE.

Objectives of the Committee for 2009 were to help members: move towards transformation; obtain a rating/pre-assessment; service and support members through workshops; and complete the first benchmarking of the transformation progress of PIASA members.

**Summary of important dates:**

- **26 May 2009** - PIASA Workshop: BB BEE status, Audit preparation and collecting supporting evidence
- **14 October 2009** - PIASA Workshop: Practical actions companies should be doing in the last 2 months of the year to ensure transformation and BEE initiatives are well positioned at year end

**Committee Members (August 2009 – August 2010):**

- Guni Goolab (AstraZeneca) – Chairperson,
- Buhle Mayo (AstraZeneca),
- Simangele Manana (Bristol-Myers Squibb),
- Jenny Wright (Galderma),
- Yvette Gengan (Galderma),
- Roger Crawford (Johnson & Johnson),
- Godwin Jacob (Merck),
- Lebo Duwo (Novo Nordisk),
- Gwen Rapetsoa (Solvay Pharma),
- Ashley Pearce (Schering-Plough),
- Nusreen Khan (Wyeth),
- Werner Pretorius (Wyeth),
- Robin Woolley (Transcend Corporate Advisors),
- Claudia Campbell (Transcend Corporate Advisors),
- and Vicki Ehrich (PIASA).

**Committee Members (August 2008 – August 2009):**

- Guni Goolab (AstraZeneca) – Chairperson,
- Buhle Mayo (AstraZeneca),
- Simangele Manana (Bristol-Myers Squibb),
- Jenny Wright (Galderma),
- Precious Maeteletsa (Galderma),
- Roger Crawford (Johnson & Johnson),
- Godwin Jacob (Merck),
- Lebo Duwo (Novo Nordisk),
- Gwen Rapetsoa (Solvay Pharma),
- Ashley Pearce (Schering-Plough),
- Nusreen Khan (Wyeth), and Vicki Ehrich (PIASA).
The Export group, led initially by Deon Vos (Merck) and then by Pierre Bosch (Alcon) was established in September 2009 to deal with members’ interests relating to exports. Potential areas of common interest were identified:

- In-market Data
- Regulatory issues and Distribution

The key priority identified by the group was to conduct research to establish the market size and potential in various markets. Organisations such as IMS were consulted but no suitable proposal was forthcoming. A pilot project to collect sales data for certain selected markets, such as Kenya, Ghana and Angola was planned with an external consultant. After careful consideration, competition issues stood in the way of progress and not only the project was abandoned, but it was decided to disband the group.

The second key issue for the group was regulatory issues. The Regulatory group, under SciTech, was already active in dealing with regulatory issues in export markets. It was decided to have representation from the now disbanded Export group, in the person of Pierre Bosch, to ensure continuity in export matters under the Regulatory group.

The potential impact of the new Customs and Excise Bill was also investigated by this group.

The group will remain as a virtual group or mailing list, should there be a need for input on Export matters.

Committee Members (from September 2009): Deon Vos, Merck (Chairman until October), Pierre Bosch, Alcon Laboratories (Chairman from November), Saras Rosin (AstraZeneca), Steven Honeyborne (GlaxoSmithKline), Steven Muller (Merck Serono), Raymond Raves (Servier), Kiril Narsai (PIASA), Paulo Pinto (Abbott), Norman Siebert (Adcock Ingram), Kiasha Naidoo (Novartis), Kevin Peddie (Janssen-Cilag), Shaun Fireson (Nusa Nordisk), David Fourie (Merck) and Vicki Ehrich (PIASA).

Local Manufacture

The Local Manufacture group, headed by Kuben Pillay (Adcock Ingram), addresses the issues of local manufacturers within the PIASA fold. Matters relating to local manufacturing incentives and how to stimulate industry investment overall was discussed with Andre Kudlinski from the dti.

Local Tenders

Local tenders – With the exception of the adjustments to volumes no changes on the published requirements for local preference for tenders / 289-MF were made. There will be no changes from the requirements already published.

As far as the adjudication of tenders is concerned 90% will be judged on price and 10% on local content.

It is possible that industry will receive blanket exemption from tender offset requirements – matter under discussion.

Tax Incentives

In September 2008 draft tax incentives for industry were made public. PIASA commented on the proposed tax incentives for local manufacture and the need to co-ordinate tax incentives with SARS.

Committee Members (August 2009 – August 2010): Kuben Pillay (Adcock Ingram) - Chairperson, Jonathan Louw (Adcock Ingram), Mahendra Chibabhai (Adcock Ingram), Bernie McDowall (Merck), Ismet Amod (Bioclones), Rob McDavid (GlaxoSmithKline), Magriet de Wet (Key Oncologics), Raymond Raves (Servier), Raseela Inderlall (NAPM), Val Beaumont (IMSA) and Vicki Ehrich (PIASA).

Committee Members (August 2008 – August 2009): Kuben Pillay (Adcock Ingram) - Chairperson, Jonathan Louw (Adcock Ingram) Mahendra Chibabhai (Adcock Ingram), Bernie McDowall (Merck), Ismet Amod (Bioclones), Rob McDavid (GlaxoSmithKline) and Vicki Ehrich (PIASA).
Health Outcomes

The Health Outcomes Committee, chaired by Jay Hooghuis (Wyeth), merged with the HEAT group because the issues dealt with overlapped. Momentum on projects therefore increased significantly during 2009. Most of the work done centered around the funding of and access to medicines and consumer protection.

### Training Workshops

Four training workshops were hosted on: the Consumer Protection Act; Dinokeng Scenarios; Medical Schemes Act; and the Companies Act.

**Companies Act** – A workshop led by Dr Mkhuseli Vimba, the dti, was held on 7 October 2009. The workshop focused on the new Companies Act and how it will affect member companies.

**Consumer Protection Act** – The HEAT group attended a dti training session, on 2 September 2009, on the Consumer Protection Act. Training was done by Carin Coode (Consumer Education and Compliance, the dti).

**Medical Schemes Act** – Representatives from the Council for Medical Schemes presented on various aspects of the Medical Schemes Act and its regulations. Speakers included Ronel Smit and Craig Burton-Durham, who focused on Prescribed Minimum Benefits and governance issues related to medical schemes.

**Dinokeng Scenarios** - Following major changes in the political environment for healthcare delivery a Scenario Team consisting of 35 South Africans from all sectors of society, including government, political parties, media, business, public administration, trade unions, academia and civil society, gathered to consider possible pathways into the future.

This was followed by various workshops around the country by appointed facilitators. On 21 October, PIASA hosted such a workshop to present the findings of the team and to also engage in debate on important issues related to the future of South Africa and healthcare industry.

### Consumer Protection Act

The group actively participated in analyzing the Act and sensitizing dti on the health impacts of the Act in the Medical Schemes setting.

PIASA’s pro-active dealings as far as the Consumer Protection Act on medical scheme funding is concerned are ongoing.

Position papers on the impact of the Consumer Protection Act in the medical schemes area were outsourced for development.

A case study project was launched to identify issues and/or irregularities related to the reimbursement of medicines by medical schemes.

The project was outsourced for reasons of data confidentiality and completion. Results are expected early in 2010.

### Medical Schemes Act

The group engaged with key stakeholders, collected data and submitted comments to the Council of Medical Schemes on governance and fit and proper standards for trustees.

The Medical Schemes Amendment Bill was placed on hold in favour of the National Health Insurance discussions.
Compliance with PMB Regulations

PIASA made comment and submissions on: the third draft of the Prescribed Minimum Benefits (PMB) consultation document (March 2009), accreditation standards for managed care organisations (October 2009), and corporate governance of medical schemes.

Following the Council for Medical Schemes (CMS) calling for nominations for the clinical advisory committees for PMBs, PIASA co-ordinated the approach to nominations.

Each PIASA member company nominated representatives from their companies. This ensured a co-ordinated approach to representation at clinical advisory committee meetings.

Summary of important dates:

- 29 April 2009 - Consumer Protection Bill published
- 2 Sept 2009 - PIASA training workshop on the Consumer Protection Act
- 28 Sept 2009 - PIASA workshop on the Medical Schemes Act, CMS view and legal framework
- 7 Oct 2009 - Companies Act training workshop
- 14 Oct 2009 - PIASA Workshop: Practical actions companies should be doing in the last 2 months of the year
- 21 Oct 2009 - Dinokeng Scenarios workshop by PIASA

Committee Members (August 2009 – August 2010): Jay Hooghuis (Wyeth) – Chairperson August 2008 to October 2009, Peter Lyons (Abbott Laboratories) – Chairperson from October 2009, Richard de Chastelain (Bayer Schering), Sohana Sukhnandan (GlaxoSmithKline), Kobus Venter (Janssen-Cilag), Tom Molokoane (Abbott Laboratories), Lindiwe Pemba (Novo Nordisk) and Kirti Narsai (PIASA).

Committee Members (August 2008 – August 2009): Jay Hooghuis (Wyeth) - Chairperson, Saras Rosin (AstraZeneca), Richard de Chastelain (Bayer Schering), Sohana Sukhnandan (GlaxoSmithKline), Kobus Venter (Janssen-Cilag), Tom Molokoane (Abbott Laboratories), Gerdi Strydom (Wyeth), Lindiwe Pemba (Novo Nordisk) and Maureen Kirkman (PIASA).
Communications

Led by Richard de Chastelain (Bayer Schering Pharma) this group remained focused on raising the profile of PIASA and its members, communicating with members and key stakeholders, building and maintaining a relationship with the media and dealing proactively with the media.

Media

Much effort was put into the communications activities with good media coverage received. Bi-monthly advertorial pages were published in the Medical Chronicle covering the Marketing Code, Transformation, Medicine Price increases and more. “Good News” stories showcasing PIASA members were included regularly on this page.

Significant coverage was received in an “Overview of Industry” in FinWeek.

51% of coverage obtained during 2009 was generated through dissemination of PIASA press releases and 49% was generated through articles written by journalists.

PIASA took advantage of opportunities for exposure by responding to special features in various publications, and presenting PIASA’s position by participating in relevant forums. The overall calculated advertising value of press coverage received for 2009 was R438 939 with a total reach of 2 094 164 persons.

Excellent speakers participated in this very successful session, with outstanding member attendance and audience participation.

PIASA Website

PIASA’S website was redesigned and relaunched in October 2009, the intention being for members to use the PIASA website as their first point of reference for PIASA information. The relaunched website provides easy access to relevant industry information such as:

- Legislation and Regulation (includes Government Gazettes)
- Submissions and comment on legislation and regulations
- Code of Marketing Practice
- Transformation
- Industry Intelligence and market data
- Events taking place
- Latest news by member companies
- Latest media news

It is further intended to be a resource for journalists and other stakeholders, providing up to date information on relevant industry topics across the board.

Member Communication

The annual information session to update members on PIASA activities was held on 6 November 2009. The programme for the 2009 Update and Briefing session was exceptional with very high caliber speakers participating. Issues covered included: the challenges of healthcare provision in South Africa; the South African National Health Insurance Model, Department of Health objectives and plans; the new regulatory authority and National Health Policy strategy for the pharmaceutical industry.

Excellent speakers participated in this very successful session, with outstanding member attendance and audience participation.

Media Monitoring

All news clippings received from the PIASA subscription to an online media monitoring service, monitoring over 60 000 global sources, were posted to the PIASA website for easy access by members.

Summary of important dates:
6 November 2009 - Update and Briefing Session

Committee Members [August 2009 - August 2010]: Richard de Chastelain (Bayer Schering Pharma) - Chairperson, Pierre Bosch (Alcon Laboratories), Mike Mabasa (Adcock Ingram), Gugu Nyandeni (Adcock Ingram), Bridget von Holdt (Inzalo Communications) and Vicki Ehrich (PIASA).

Committee Members [August 2008 - August 2009]: Richard de Chastelain (Bayer Schering Pharma) - Chairperson, Pierre Bosch (Alcon Laboratories), Kuben Pillay (Adcock Ingram), Elvis Mokoena (GlaxoSmithKline) and Vicki Ehrich (PIASA).
Committee for Science and Technology (SciTech)

The SciTech Committee, led by Kobus Venter (Janssen-Cilag), mainly analyse and interpret legislation and international trends for member companies. The Committee prepares comment and submissions on legislation, regulations or guidelines to Government Departments or other stakeholders.

The four working groups i.e. Regulatory, Pharmacovigilance, Quality Management and Clinical were very active and had regular meetings. A survey was conducted to determine the level of satisfaction of members of the working groups in terms of added value to their work. Forty three people completed the survey with excellent ratings.

Quality Management Working Group
Chair: Helen Sophos (Novo Nordisk)

The focus areas of the Quality Management Working Group for 2009 were: Good Manufacturing Practice (GMP); distribution, theft and counterfeiting; and medical waste.

**Good Manufacturing Practice**

Submissions were made to the Medicines Control Council (MCC) on the revised Good Manufacturing Practice (GMP) guidelines which were published for comment.

A submission was also made to MCC regarding a recently published stability guideline which has serious implications for member companies’ stability programs.

**Distribution, Theft and Counterfeiting**

A very successful Counterfeit Medicines Workshop was held on 17 July 2009 with speakers i.e. Griffith Molewa (DoH) and Johan Bothma (PSSA). Members of PIASA, IMSA, wholesalers as well companies responsible for the destruction of medicines attended.

Responses to the post workshop survey were very positive. Actions coming out of the workshop included the review and updating of the drug destruction guidelines.

**Risk Management**

The group initiated a Quality Risk Management project, which addressed requirements from the MCC, ICH and GMP. The group is developing practical tools that can be implemented in companies in order to comply with risk management requirements for audit purposes.

A proposed worksheet detailing: Probability, Impact, Risk score, Mitigation and Avoidance has been developed. The 1st five practical examples, (Product Release, Labelling Approval, Distribution, Returns and Marketing Material Approval) were completed by the group and have been circulated to members.
Regulatory Affairs Working Group
Chair: Abeda Williams (Janssen-Cilag)

The highlights of the work done by the Regulatory Affairs Working Group during 2009 were:
- Submissions and presentations to ministerial task teams on regulatory issues
- Medicine Control Council (MCC) Workshop
- Proposals/submissions to MCC
- Namibian Labeling
- Harmonisation

**Regulatory Submissions**

This group has been very active in commenting on various technical guidelines that have been published by the Medicines Control Council (MCC) and continues to follow-up on submissions made to the MCC. Other submissions included proposals on: SR-PINs, PILs, proprietary names and recall of medicines.

PIASA further contributed to the Medical Products Technical Task Team (appointed by the Minister and chaired by Precious Matsoso) on regulatory issues experienced by the industry through various sessions and submissions. A comprehensive submission made to the MPTTT recommending a regulatory system whereby recognition of approval by benchmark regulatory authorities is considered.

**New Medicines Control Legislation**

After intensive interaction with the Ministerial Task Team (MTT) during 2006 and 2007 the Medicines and Related Substances Control Amendment Bill, which included a proposed two-tier system of registration for the approval of medicines giving the Minister of Health final decision making powers over the registration of medicines was published in 2008. This was completely unacceptable to PIASA members.

Publication of the Bill was thus followed by a period of intense activity which included meetings and submissions by role players resulting in a revised Bill, published on 2 June 2008, which still retained certain clauses unacceptable to industry including the proposal for a two-tier approval system.

PIASA then made a number of submissions and presentations, held meetings with the Portfolio Committee on Health, the opposition parties and key stakeholders to present arguments opposing those clauses and to recommend measures to improve and expedite the approval process.

This active involvement industry role players succeeded in convincing the Committee to eliminate the Minister of Health’s decision making powers on registration and the Department of Health was directed to redraft the Bill.

The amended Act was published and new regulations which will give effect to the amended Act are pending.

PIASA continued to pursue the backlog in medicine registration and the effect thereof on the industry.

MCC was requested that the clearing of the backlog be treated as Phase One Spreadsheets were circulated to PIASA members, by the MCC, to complete regarding backlog issues.

The following issues will be looked at:
- Key changes to the Act i.e. should the Minister of Health consider removing any pricing regulations from the Medicines Act to the National Health Act
- Any possible constitutionality issues that could be raised
- Key areas we should focus on with reference to the regulations and guidelines
- Any other issues we need to take into consideration
- Medical devices and other medicines.

**Registration of Medicines**

PIASA Workshop on registration issues was well attended by industry.
At the workshop held by MCC on 3rd November 2009 PIASA reiterated its previous recommendations made to the MCC to improve operational efficiencies.

The workshop was held to discuss areas of improvement to allow for better and faster processing of applications for medicine registration/clinical trial authorisations within the office of the MRA/MCC and the pharmaceutical industry.

MCC intends to have 2 to 3 workshops per year addressing all problems experienced by industry. Suggested topics to be addressed at the 2010 MCC Workshops will be submitted by PIASA to the MCC early in January 2010.

**Summary of important dates:**
- 25 Feb 2008 - Publication of Ministerial Task Team report
- 18 April 2008 - Publication of draft National Health Bill
- 2 June 2008 - Revised Bill published
- 21 April 2009 - The amended Act and Regulations were published – Government Gazette 32148

**Clinical Working Group**

Chair: Darren Katzman (MSD/Schering-Plough)

The Clinical Working Group focused on promoting clinical trials and influencing key stakeholders to improve the efficiency of the regulatory environment in order to attract more clinical trials to South Africa. The Group successfully lobbied the South African Revenue Service (SARS) and DST for the recognition of clinical trials as a legitimate Research and Development (R&D) activity in order to qualify for tax incentives. The objectives of the group for 2010 is to market South Africa for clinical research as a destination of choice for clinical research, and to positively influence technical and policy issues impacting clinical trials in SA.

**Tax Incentives**

The greatest achievement in this group has been to successfully challenge the South African Revenue Service (SARS) on the exclusion of clinical trials from the Draft Interpretation Note on Tax Incentives for R&D activities.

The latest version of the SARS Draft Interpretation Note, published towards the end of 2009, in terms of clinical trials, included Phase 1, 2 and 3 trials as legitimate R&D activities, but not Phase 4 clinical trials.

**Clinical Trial Workshop**

A Clinical Workshop was held on 13 October 2009. Dr Rajen Misra, MCC, was a key speaker and he was open to questions and discussions on the future of clinical trials in South Africa as well as the rollout of an electronic document management system for clinical trial submissions. Savi Chetty (Consultant from SCT) also presented at the workshop on unit standards for CRA’s. Industry was given an opportunity to comment on the unit standards for CRA’s. The Clinical Workshop was a huge success with delegates from various associations attending.

**Labeling**

PIASA negotiated a very successful meeting between the Namibian Registrar and the South African Registrar to discuss the changes in Namibian legislation requiring Namibian registration details on medicine packs sold in Namibia. This resulted in approval received from MCC to add this on the South African packaging and an extension on the deadline for implementation of the Namibian labeling requirements.

A similar discussion has taken place with the Kenyan’s regulatory authority which resulted in them suspending their requirements.
During 2009, a need was identified for a new working group focusing on pharmacovigilance. The newly created group carried the responsibility of staying abreast of pharmacovigilance reporting, and promoting the use of international pharmacovigilance reporting standards in South Africa and other African countries. The group reviewed the pharmacovigilance requirements in South Africa and other African countries.

**ADR Guidelines**

The first project embarked on was the updating of the ADR Guidelines to bring it in line with international standards. A revised ADR Guideline was proposed to the Medicines Control Council (MCC) and was very well received. IMSA endorsement of the proposal was also obtained. Comments were made to the NMRC (Namibian regulatory authority) on their draft pharmacovigilance guideline. A comprehensive database has been established by the group outlining reporting requirements for African countries which members can use as a reference guide for reporting.

**Pharmacovigilance Workshop**

A combined PIASA, IMSA and SAAPI Pharmacovigilance Workshop was held on 8 June 2009. Topics covered included: Risk Management; Electronic Reporting in Europe; Safety Reporting in Pre and Post Marketing Stages; Drug Safety Management; Drug Interactions; and Industry Perspective.

From feedback received the workshop was of great benefit to attendees.

**SciTech Committee members**

**Committee Members (August 2009 – August 2010):** Chairperson: Kobus Venter (Janssen-Cilag), Ronel Coetzee (Bayer Schering Pharma), Abeda Williams (Janssen-Cilag), Helen Sophos (Novo Nordisk), Lynette Terblanche (Schering-Plough), Darren Katzman (Schering-Plough), and Kirti Narsai (PIASA).

SciTech members were supported by a large number of people drawn from member companies.
Adherence to the PIASA Code of Marketing Practice is a condition of membership for all PIASA member companies. The PIASA Marketing Code Committee has been focusing on PIASA input into the draft SA Code on the Marketing of Medicines via the Marketing Code Steering committee, which has broad representation across trade associations. The PIASA Marketing Code Committee has also been active in commenting on international WHO documents published on marketing code issues via the IFPMA. PIASA is also represented on the IFPMA Code Compliance Network of the IFPMA.

**Marketing Code Workshop**

In a strong show of commitment to global ethical marketing practices, over 60 representatives of the pharmaceutical industry attended a marketing code workshop hosted by PIASA (Pharmaceutical Industry Association of South Africa) and attended by DoH representative, Dr Joey Gouws.

We were fortunate to secure Mr Richard Bergstrom, Director General of LIF in Sweden (also the advisor to the World Health Organisation) as a speaker on the IFPMA Code of Marketing Practices at this workshop held in March 2009.

**Global Code Compliance Survey**

PIASA further participated in the Global Code Compliance Survey which focused on comparing requirements of Codes around the world using a scoring system with a maximum score of 34. South Africa scored 32, compared to USA with 24, UK on par with 32.

**IFPMA CNN Meeting**

PIASA is presented on the IFPMA Code Compliance Network, the Scoping group as well as the Code Advocacy group. PIASA presented on the South African Code at the IFPMA CCN meeting in Washington on 4 May 2009 and May 2009.

**Committee Members (August 2009 – August 2010):** Eric Reurts (Novo Nordisk) – Chairperson. Members: Louendrie Pillay (AstraZeneca), Abeda Williams (Janssen-Cilag), Lynette Terblanche (Schering-Plough) and Kirti Narsai (PIASA).

**Committee Members (August 2008 – August 2009):** Deon Vos (Merck) – Chairperson. Members: Kobus Venter (Janssen-Cilag), Abeda Williams (Janssen-Cilag), Lynette Terblanche (Schering-Plough) and Maureen Kirkman (PIASA).
The financial affairs of the association remained well controlled and well within budget. A satisfactory audit report was received and is detailed in the following pages. The most significant financial highlights are summarized hereunder:

**Overall Financial Results**

The Association posted an audited surplus of R 533 831 for the financial year under review, in comparison with a prior year surplus of R 550 167.

### Income

**Subscription Income** - The membership subscriptions for 2009 were increased by 8%, as approved by members of the Annual General Meeting held in 2008.

The income received from subscriptions for the year was R7 085 470, compared to R6 349 980 in 2008. The increase of 11.58% in the face of the 8% increase was partially due to the loss of three members, the balance was due to several member firms changing categories during the year under review.

**Other Income** - came from workshops held and interest on bank balances. Interest received was under budget by R43 338.

### Expenses

**Operating Expenses**

The total operating expenses remained tightly controlled and ended well below budget.

- **Personnel Costs**

  The Association’s payroll costs were 22.80% higher in 2009 moving from R2 788 174 in 2008 to R3 424 118 in 2009. Which exceeded budget of R3 279 371. The increase was attributable to an approved annual increase in salaries, the use of M Kirkman as a consultant and an increase provision for leave pay.

- **Committee Expenses**

  The majority of the committee expenses related to draft pricing. The total cost incurred was R695 417. No special levy was raised.

**Capital Expenditure**

The net cash used in capital expenditure was R154 316, exceeding the budget of R130 000.

Due to the development of the website there was overspending. This expense was not foreseen nor budgeted for.

The balance of the funds was spent on the audio system for the board room.

### Accounts Receivable

The accounts receivable of the Association remained well controlled.

All subscriptions invoiced during the year were collected by year end.

### Cash Management

At year-end, the cash resources of the Association amounted to R8 092 285 exceeding the prior year’s balance of R7 329 914.

Most of the Association’s funds are retained in interest bearing investments in order to maximize the return thereon for the Association.
ANNUAL FINANCIAL STATEMENTS:
Pharmaceutical Industry Association of SA
For the year ended 31 December 2009

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Directors’ responsibility statement

The directors are responsible for the preparation and fair presentation of the annual financial statements of The Pharmaceutical Industry Association of South Africa, comprising the statement of financial position at 31 December 2009, and the statement of comprehensive income, the statement of changes in equity and cash flow statement for the year then ended, and the notes to the financial statements, which include a summary of significant accounting policies and other explanatory notes, and the directors’ report, in accordance with South African Statements of Generally Accepted Accounting Practice and in the manner required by the Companies Act of South Africa.

The directors’ responsibility includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of these financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

The directors’ responsibility also includes maintaining adequate accounting records and an effective system of risk management.

The directors have made an assessment of the company’s ability to continue as a going concern and have no reason to believe the business will not be a going concern in the year ahead.

The auditor is responsible for reporting on whether the annual financial statements are fairly presented in accordance with the applicable financial reporting framework.

Approval of the annual financial statements

The annual financial statements of the Pharmaceutical Industry Association of South Africa, as identified in the first paragraph, were approved by the board of directors on 4 August 2010.
Independent auditor’s report
To the members of the Pharmaceutical Industry Association of South Africa

We have audited the annual financial statements of the Pharmaceutical Industry Association of South Africa, which comprise the statement of financial position at 31 December 2009, and the statement of comprehensive income, the statement of changes in equity and statement of cash flows for the year then ended, and the notes to the financial statements, which include a summary of significant accounting policies and other explanatory notes, and the directors’ report.

Directors’ responsibility for the financial statements

The company’s directors are responsible for the preparation and fair presentation of these financial statements in accordance with South African Statements of Generally Accepted Accounting Practice and in the manner required by the Companies Act of South Africa. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor’s responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor’s judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity’s preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Pharmaceutical Industry Association of South Africa at 31 December 2009, and its financial performance and cash flows for the year then ended in accordance with South African Statements of Generally Accepted Accounting Practice, and in the manner required by the Companies Act of South Africa.

KPMG Inc.

Per C Swart
Chartered Accountant (SA)
Registered Auditor
Director
30 April 2010
The directors have pleasure in presenting their report for the year ended 31 December 2009.

**Nature of business**

The Association is incorporated in the Republic of South Africa. The Association’s objective is to promote the pharmaceutical industry at all times.

**General review**

The results of the Association’s operations, for the year ended 31 December 2009, are adequately disclosed in the accompanying annual financial statements. In 2006 the Association changed its name from Pharmaceutical Manufacturers’ Association of South Africa to The Pharmaceutical Industry Association of South Africa.

**Directors**

The following acted as directors during the year and to the date of the report –

- J Louw
- G Goolab
- RA De Chastelain
- AM Pearce
- JD Venter
- E Reurts
- I Amod
- P Lyons
- D Vos (resigned 29 October 2009)
- JW Hooghuys (resigned 19 October 2009)
- P Bosch (appointed 21 October 2009)

**Secretary**

The secretary of the company is Vexillum (Proprietary) Limited. Their registered and postal addresses are as follows:

<table>
<thead>
<tr>
<th>Registered address</th>
<th>Postal address</th>
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<tbody>
<tr>
<td>11B Riley Road</td>
<td>PO Box 781907</td>
</tr>
<tr>
<td>Eastwood Office Park</td>
<td>Sandton</td>
</tr>
<tr>
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### Statement of financial position

#### Assets

<table>
<thead>
<tr>
<th>Note</th>
<th>2009 R</th>
<th>2008 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-current asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>3</td>
<td>279 413</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>4</td>
<td>69 500</td>
</tr>
<tr>
<td>Current assets</td>
<td></td>
<td>8 413 036</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>5</td>
<td>320 751</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>6</td>
<td>8 092 285</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td></td>
<td><strong>8 761 949</strong></td>
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</tbody>
</table>

#### Equity

<table>
<thead>
<tr>
<th>Note</th>
<th>2009 R</th>
<th>2008 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reserves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accumulated funds</td>
<td></td>
<td>8 031 383</td>
</tr>
<tr>
<td>Current liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>7</td>
<td>730 566</td>
</tr>
<tr>
<td><strong>Total equity and liabilities</strong></td>
<td></td>
<td><strong>8 761 949</strong></td>
</tr>
</tbody>
</table>

### Statement of comprehensive income

<table>
<thead>
<tr>
<th>Note</th>
<th>2009 R</th>
<th>2008 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>8</td>
<td>7 191 488</td>
</tr>
<tr>
<td>Expenditure</td>
<td></td>
<td>(7 294 319)</td>
</tr>
<tr>
<td>Excess of revenue over expenditure before finance income</td>
<td>10</td>
<td>(102 831)</td>
</tr>
<tr>
<td>Finance income</td>
<td>9</td>
<td>636 662</td>
</tr>
<tr>
<td>Excess of revenue over expenditure for the year</td>
<td></td>
<td>533 831</td>
</tr>
<tr>
<td>Other comprehensive income for the period</td>
<td></td>
<td>–</td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td></td>
<td><strong>533 831</strong></td>
</tr>
</tbody>
</table>
Statement of changes in equity

<table>
<thead>
<tr>
<th></th>
<th>Accumulated funds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R</td>
</tr>
<tr>
<td>Balance at 31 December 2007</td>
<td>6 947 385</td>
</tr>
<tr>
<td>Total comprehensive income for</td>
<td>550 167</td>
</tr>
<tr>
<td>the period</td>
<td></td>
</tr>
<tr>
<td>Profit for the year</td>
<td>550 167</td>
</tr>
<tr>
<td>Balance at 31 December 2008</td>
<td>7 497 552</td>
</tr>
<tr>
<td>Total comprehensive income for</td>
<td>533 831</td>
</tr>
<tr>
<td>the period</td>
<td></td>
</tr>
<tr>
<td>Profit for the year</td>
<td>533 831</td>
</tr>
<tr>
<td>Balance at 31 December 2009</td>
<td>8 031 383</td>
</tr>
</tbody>
</table>

Cash flow statement

<table>
<thead>
<tr>
<th>Cash flow from operating activities</th>
<th>R</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit for the period</td>
<td>533 831</td>
<td>550 167</td>
</tr>
<tr>
<td>Adjustment for:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>158 379</td>
<td>69 992</td>
</tr>
<tr>
<td>Interest received</td>
<td>(636 662)</td>
<td>(708 731)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>55 548</td>
<td>(88 572)</td>
</tr>
<tr>
<td>Change in trade and other receivables</td>
<td>58 610</td>
<td>(123 522)</td>
</tr>
<tr>
<td>Change in trade and other payables</td>
<td>175 867</td>
<td>47 097</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>290 025</td>
<td>(164 997)</td>
</tr>
</tbody>
</table>

Cash flows from investing activities

| Interest received                  | 636 662 | 708 731 |
| Equipment acquired                 | (154 316) | (213 591) |
|                                    | 772 371  | 330 143 |
|                                    |         |         |
| Cash and cash equivalents at beginning of year | 7 319 914 | 6 989 771 |
| Cash and cash equivalents end of year | 8 092 285 | 7 319 914 |
1. **Accounting policies**

The annual financial statements are prepared on the historical cost basis, and incorporate the following principal accounting policies which are consistent with those adopted in the previous year.

1.1 **Basis of preparation**

The annual financial statements are prepared in accordance with the requirements of South African Statements of Generally Accepted Accounting Practice and the requirements of the Companies Act of South Africa. The annual financial statements are prepared on a going concern basis.

1.2 **Property, plant and equipment**

Property, plant and equipment are stated at cost less accumulated depreciation and are depreciated at the following rates per annum on the reducing-balance method, which is based on the estimated economic lives of the related assets:

- Motor vehicles: 20%
- Furniture and fittings: 15%
- Computer equipment: 33.33%
- Office equipment: 25%
- Leasehold improvements: 20%

The initial cost of the fixed assets comprises its purchase price, and any directly attributable costs of bringing the asset to its working condition and location for its intended use. Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are normally charged to income in the period in which the costs are incurred.

In situations where it can be clearly demonstrated that the expenditures have resulted in an increase in the future economic benefits expected to be obtained from the use of the fixed asset beyond its originally assessed standard of performance, the expenditures are capitalised as an additional cost of the fixed asset.

1.3 **Intangible assets**

Intangible assets acquired by the company which have finite useful lives, are measured at cost less accumulated amortisation and accumulated impairment losses.

Subsequent expenditure is capitalised only when it increases the future economic benefits embodied in the specific asset to which it relates. All other expenditure is recognised in profit or loss when incurred.

The useful life and residual value is reassessed on an annual basis for appropriateness.

Amortisation is recognised in profit or loss on the reducing-balance method basis over the estimated useful lives of intangible assets, from the date they are available for use. The estimated useful life for computer software is 3 years.

1.4 **Impairment of assets**

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Whenever the carrying amount of an asset exceeds its recoverable amount, an impairment loss is recognised in income for fixed assets carried at cost.

The recoverable amount is the higher of an asset’s net selling price and value in use. The net selling price is the amount obtainable from the sale of an asset in an arm’s length transaction while value in use is the present value of estimated future cash flows expected to arise from the continuing use of an asset and from its disposal at the end of its useful life.
1.5 **Cash and cash equivalents**

Cash includes cash on hand and cash with banks.

1.6 **Financial Instruments**

*Initial recognition*

The company classifies financial instruments, or their component parts, on initial recognition as a financial asset, a financial liability or an equity instrument in accordance with the substance of the contractual arrangement.

Financial assets and financial liabilities are recognised on the company’s statement of financial position when the company becomes party to the contractual provisions of the instrument.

*Trade and other receivables*

Trade receivables are measured at initial recognition at fair value, and are subsequently measured at amortised cost using the effective interest rate method. Appropriate allowances for estimated irrecoverable amounts are recognised in profit or loss when there is objective evidence that the asset is impaired. The allowance recognised is measured as the difference between the asset’s carrying amount and the present value of estimated future cash flows discounted at the effective interest rate computed at initial recognition.

*Trade and other payables*

Trade payables are initially measured at fair value, and are subsequently measured at amortised cost, using the effective interest rate method.

*Cash and cash equivalents*

Cash and cash equivalents comprise cash on hand and demand deposits, and other short-term highly liquid investments that are readily convertible to a known amount of cash and are subject to an insignificant risk of changes in value. These are initially and subsequently recorded at fair value.

*Bank overdraft and borrowings*

Bank overdrafts and borrowings are initially measured at fair value, and are subsequently measured at amortised cost, using the effective interest rate method. Any difference between the proceeds (net of transaction costs) and the settlement of redemption of borrowings is recognised over the term of the borrowings in accordance with the company’s accounting policy for borrowing costs.

1.7 **Revenue**

Revenue, which excludes value added taxation, represents the invoiced value of subscription, income, training course fees and other sundry income.

1.8 **Finance Income**

Finance income comprises interest income on funds invested. Interest income is recognised as it accrues, using the effective interest method.

1.9 **Operating Lease**

Leases of assets under which all the risks and rewards of ownership are effectively retained by the lessor are classified as operating leases. Lease payments under an operating lease are recognised as an expense on a straight-line basis over the lease term.
2. **Financial risk management**

**Overview**

The association has exposure to the following risks from its use of financial instruments:

- Credit risk
- Liquidity risk
- Market risk

This note presents information about the association’s exposure to each of the above risks, the association’s objectives, policies and processes for measuring and managing risk and the association’s management of capital. Further quantitative disclosures are included throughout these financial statements.

**Credit risk**

Credit risk is the risk of financial loss to the association if a member or counterparty to a financial instrument fails to meet its contractual obligations, and arises principally from the association’s receivables from member and investments securities.

**Trade and other receivables**

The association’s exposure to credit risk is influenced mainly by the individual characteristics of each member.

**Allowance for impairment**

The association establishes an allowance for impairment that represents its estimate of incurred losses in respect of trade and other receivables and investments.

**Investments**

The association limits its exposure to credit risk by only investing in liquid securities and only with major financial institutions in the country.

**Liquidity risk**

Liquidity risk is the risk that the association will not be able to meet its financial obligations as they fall due. The association’s approach to minimising liquidity risk is to ensure, as far as possible, that it has adequate banking facilities and reserve borrowing capacity to meet its liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the association’s reputation.

**Market risk**

Market risk is the risk that changes in the market prices, such as foreign exchange rates, interest rates and equity prices will affect the association’s income or the value of its holdings of financial instruments.

**Currency risk**

The association has limited exposure to currency risk as the majority of the association’s transactions are in local currency.

**Interest rate risk**

As part of the process of managing the association’s interest rate risk, interest rate characteristics of new borrowings and the refinancing of existing borrowings are positioned according to expected movements in interest rates.

**Capital management**

Management’s policy is to maintain a strong capital base so as to maintain creditor confidence and to sustain future development of the business.
### 3. Equipment

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Furniture and fittings</td>
<td>Computer equipment</td>
<td>Office equipment</td>
<td>Leasehold improvements</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td><strong>Beginning of the year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– cost</td>
<td>455 052</td>
<td>577 634</td>
<td>35 219</td>
<td>1 144 986</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– accumulated depreciation</td>
<td>(201 464)</td>
<td>(511 050)</td>
<td>(32 589)</td>
<td>(46 907)</td>
<td>(792 010)</td>
<td></td>
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<tr>
<td>Opening carrying value</td>
<td>253 588</td>
<td>66 584</td>
<td>2 630</td>
<td>30 174</td>
<td>352 976</td>
<td></td>
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<tr>
<td><strong>Current year movements</strong></td>
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<tr>
<td>– additions</td>
<td>84 816</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>84 816</td>
</tr>
<tr>
<td>– depreciation</td>
<td>(100 487)</td>
<td>(44 226)</td>
<td>(2 630)</td>
<td>(11 036)</td>
<td>(158 379)</td>
<td></td>
</tr>
<tr>
<td>Closing carrying value</td>
<td>237 917</td>
<td>22 358</td>
<td>-</td>
<td>19 138</td>
<td>279 413</td>
<td></td>
</tr>
<tr>
<td><strong>Made up as follows:</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– cost</td>
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<td>577 634</td>
<td>35 219</td>
<td>77 081</td>
<td>1 229 802</td>
<td></td>
</tr>
<tr>
<td>– accumulated depreciation</td>
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<td>(555 276)</td>
<td>(35 219)</td>
<td>(57 943)</td>
<td>(950 389)</td>
<td></td>
</tr>
<tr>
<td>Closing carrying value</td>
<td>237 917</td>
<td>22 358</td>
<td>-</td>
<td>19 138</td>
<td>279 413</td>
<td></td>
</tr>
<tr>
<td><strong>2008</strong></td>
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<tr>
<td><strong>Beginning of the year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– cost</td>
<td>274 511</td>
<td>577 634</td>
<td>35 219</td>
<td>44 031</td>
<td>931 395</td>
<td></td>
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<td>– accumulated depreciation</td>
<td>(172 530)</td>
<td>(477 757)</td>
<td>(31 713)</td>
<td>(40 018)</td>
<td>(722 018)</td>
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<td>99 877</td>
<td>3 506</td>
<td>4 013</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– additions</td>
<td>180 541</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>33 050</td>
<td>213 591</td>
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<tr>
<td>– depreciation</td>
<td>(28 934)</td>
<td>(33 293)</td>
<td>(876)</td>
<td>(6 889)</td>
<td>(69 992)</td>
<td></td>
</tr>
<tr>
<td>Closing carrying value</td>
<td>253 588</td>
<td>66 584</td>
<td>2 630</td>
<td>30 174</td>
<td>352 976</td>
<td></td>
</tr>
<tr>
<td><strong>Made up as follows:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– cost</td>
<td>455 052</td>
<td>577 634</td>
<td>35 219</td>
<td>77 081</td>
<td>1 144 986</td>
<td></td>
</tr>
<tr>
<td>– accumulated depreciation</td>
<td>(201 464)</td>
<td>(511 050)</td>
<td>(32 589)</td>
<td>(46 907)</td>
<td>(792 010)</td>
<td></td>
</tr>
<tr>
<td>Closing carrying value</td>
<td>253 588</td>
<td>66 584</td>
<td>2 630</td>
<td>30 174</td>
<td>352 976</td>
<td></td>
</tr>
</tbody>
</table>
4. **Intangible assets**

<table>
<thead>
<tr>
<th></th>
<th>Accumulated depreciation</th>
<th>Carrying value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>R</td>
</tr>
<tr>
<td>Website cost</td>
<td>69 500</td>
<td>–</td>
</tr>
<tr>
<td>2008</td>
<td>Website cost</td>
<td>–</td>
</tr>
</tbody>
</table>

Website was acquired in the month of December and has not yet been brought to use.

5. **Trade and other receivables**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade receivables</td>
<td>111 375</td>
<td>-</td>
</tr>
<tr>
<td>Less: Impairment of trade receivables</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Prepayments</td>
<td>72 536</td>
<td>61 814</td>
</tr>
<tr>
<td>Other receivables</td>
<td>137 020</td>
<td>317 547</td>
</tr>
<tr>
<td></td>
<td>320 751</td>
<td>379 361</td>
</tr>
</tbody>
</table>

6. **Cash and cash equivalents**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bank balances and cash</td>
<td>604 863</td>
<td>650 298</td>
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<tr>
<td>Short term investments</td>
<td>7 487 422</td>
<td>6 669 616</td>
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<tr>
<td></td>
<td>8 092 285</td>
<td>7 319 914</td>
</tr>
</tbody>
</table>

7. **Trade and other payables**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accruals</td>
<td>260 834</td>
<td>106 660</td>
</tr>
<tr>
<td>Sundry creditors</td>
<td>124 151</td>
<td>115 929</td>
</tr>
<tr>
<td>Trade payables</td>
<td>73 726</td>
<td>23 651</td>
</tr>
<tr>
<td>Income received in advance</td>
<td>271 855</td>
<td>308 459</td>
</tr>
<tr>
<td></td>
<td>730 566</td>
<td>554 699</td>
</tr>
</tbody>
</table>

8. **Revenue**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subscription income</td>
<td>7 085 470</td>
<td>6 349 980</td>
</tr>
<tr>
<td>Sundry income</td>
<td>106 018</td>
<td>190 283</td>
</tr>
<tr>
<td></td>
<td>7 191 488</td>
<td>6 540 263</td>
</tr>
</tbody>
</table>

9. **Finance income**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest on investments</td>
<td>636 662</td>
<td>708 731</td>
</tr>
</tbody>
</table>
10. **Excess of revenue over expenditure before finance income**

Excess of revenue over expenditure before finance income is arrived at after charging –

<table>
<thead>
<tr>
<th>Account</th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounting fees</td>
<td>221 807</td>
<td>202 178</td>
</tr>
<tr>
<td>Auditor’s remuneration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Audit fee</td>
<td>92 710</td>
<td>106 902</td>
</tr>
<tr>
<td>Depreciation</td>
<td>158 379</td>
<td>69 992</td>
</tr>
<tr>
<td>Legal fees</td>
<td>22 921</td>
<td>184 725</td>
</tr>
<tr>
<td>Rental</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Office equipment</td>
<td>406 231</td>
<td>443 747</td>
</tr>
<tr>
<td>- premises</td>
<td>519 668</td>
<td>442 639</td>
</tr>
<tr>
<td>Consulting fee</td>
<td>84 072</td>
<td>-</td>
</tr>
</tbody>
</table>

11. **Taxation**

The Association received its confirmation of continued exemption in respect of Section 10(1)(d)(iv)(bb) of the Income Tax Act. The company was last assessed in the 2005 tax year–

12. **Lease commitments**

The Association has operating lease commitments in respect of buildings and office equipment payable as follows:

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Due within a year</td>
<td>525 472</td>
<td>475 177</td>
</tr>
<tr>
<td>Due thereafter</td>
<td>1 011 068</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1 536 540</td>
<td>475 177</td>
</tr>
</tbody>
</table>

13. **Capital commitments**

Computer equipment

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17 500</td>
</tr>
<tr>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

14. **Financial instruments**

**Credit Risk**

*Exposure to credit risk*

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk at the reporting date was:

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade receivables</td>
<td>111 375</td>
<td>-</td>
</tr>
<tr>
<td>Other trade receivables</td>
<td>209 376</td>
<td>379 361</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>8 150 722</td>
<td>7 319 914</td>
</tr>
<tr>
<td></td>
<td>8 471 473</td>
<td>7 319 914</td>
</tr>
</tbody>
</table>

*All trade receivables at the reporting date were domestic in nature*
**Impairment losses**

The ageing of trade receivables at the reporting date was:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>30 – 60 days</td>
<td>82 875 R</td>
<td>- R</td>
<td>- R</td>
<td>- R</td>
</tr>
<tr>
<td>60 – 90 days</td>
<td>28 500 R</td>
<td>- R</td>
<td>- R</td>
<td>- R</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>111 375 R</strong></td>
<td><strong>- R</strong></td>
<td><strong>- R</strong></td>
<td><strong>- R</strong></td>
</tr>
</tbody>
</table>

**Credit Risk**

**Liquidity risk**

The following are the contractual maturities of financial liabilities, including interest payments and excluding the impact of netting agreements:

<table>
<thead>
<tr>
<th>31 December 2009</th>
<th>Carrying amount</th>
<th>Contractual Cash flows</th>
<th>6 months or less</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-derivative financial liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>730 566 R</td>
<td>730 566 R</td>
<td>730 566</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>31 December 2008</th>
<th>Carrying amount</th>
<th>Contractual Cash flows</th>
<th>6 months or less</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-derivative financial liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>554 699 R</td>
<td>554 699 R</td>
<td>554 699</td>
</tr>
</tbody>
</table>

**Fair values**

**Fair values versus carrying amounts**

The fair values of financial assets and liabilities, together with the carrying amounts shown in the statement of financial position, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2009 Carrying amount</th>
<th>2009 Fair value</th>
<th>2008 Carrying amount</th>
<th>2008 Fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other receivables</td>
<td>320 751 R</td>
<td>320 751 R</td>
<td>379 361 R</td>
<td>379 361 R</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>8 150 722 R</td>
<td>8 150 722 R</td>
<td>7 319 914 R</td>
<td>7 319 914 R</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>8 471 473 R</strong></td>
<td><strong>8 471 473 R</strong></td>
<td><strong>7 699 275 R</strong></td>
<td><strong>7 699 275 R</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2009 Carrying amount</th>
<th>2009 Fair value</th>
<th>2008 Carrying amount</th>
<th>2008 Fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other payables</td>
<td>(730 566) R</td>
<td>(730 566) R</td>
<td>(554 699) R</td>
<td>(554 699) R</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7 740 907 R</strong></td>
<td><strong>7 740 907 R</strong></td>
<td><strong>7 144 576 R</strong></td>
<td><strong>7 144 576 R</strong></td>
</tr>
</tbody>
</table>
### 15. Standards and interpretations not yet effective

<table>
<thead>
<tr>
<th>Standard/Interpretation</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAS 24 (AC 126) (revised) Related Party Disclosures</td>
<td>Annual periods beginning on or after 1 January 2011</td>
</tr>
<tr>
<td>There are 15 individual amendments to 12 standards. Improvements to International Financial Reporting Standards 2009</td>
<td>Amendments are effective for annual periods beginning on or after 1 January 2010, or for annual periods beginning on or after 1 July 2009 *</td>
</tr>
<tr>
<td>IFRS 1 (AC 138) amendment Additional Exemptions for First-time Adopters</td>
<td>Annual periods beginning on or after 1 January 2010*</td>
</tr>
<tr>
<td>IFRS 1 (AC 138) amendment First-time adoption of International Financial Reporting Standards</td>
<td>Annual periods beginning on or after 1 July 2010</td>
</tr>
<tr>
<td>IFRS 2 (AC 139) amendment Group Cash-settled Share-based Payment</td>
<td>Annual periods beginning on or after 1 January 2010*</td>
</tr>
<tr>
<td>IFRS 9 (AC 146)</td>
<td>Financial Instruments</td>
</tr>
<tr>
<td>IFRIC 14 (AC 447) amendment Prepayments of a Minimum Funding Requirement</td>
<td>Annual periods beginning on or after 1 January 2011</td>
</tr>
<tr>
<td>IFRIC 19 (AC 452)</td>
<td>Extinguishing Financial Liabilities with Equity Instruments</td>
</tr>
</tbody>
</table>

All Standards and Interpretations will be adopted at their effective date (except for the effect of those standards that are not applicable to the entity).

The association will present all non-owner changes in equity in a single statement of comprehensive income (which will include the current statement of comprehensive income).
Past Presidents

1967/68  Mr N R Tuck  1994/95  Dr G L Faber
1968/69  Mr A Sachs  1995/96  Mr M C Norris
1969/70  Mr A Sachs  1996/97  Mr M C Norris
1970/71  Mr A L Birchley  1997/98  Mr R de Chastelain
1971/72  Mr A L Birchley  1998/99  Mr R de Chastelain
1972/73  Mr A Sachs  1999/00  Mr R de Chastelain
1973/74  Mr A Sachs  2000/01  Mr R de Chastelain
1974/75  Mr C E Barrelett  2001/02  Mr R de Chastelain
1975/76  Mr C E Barrelett  2002/03  Ms E Mann
         Mr A V Trentham  Mr R de Chastelain
1976/77  Dr H H Snyckers  2003/04  no President only presidents council:
1977/78  Dr H H Snyckers  Mr M Spector
1978/79  Mr D C Bodley  Mr JD Venter
1979/80  Mr D C Bodley  Mr A Wish
1980/81  Mr D C Bodley  2004/05  Mr M Spector
1981/82  Mr D C Bodley  2005/06  Dr G Goolab
1982/83  Dr H H Snyckers  2006/07  Mr A Pearce
1983/84  Dr H H Snyckers  2007/08  Mr A Pearce
1984/85  Dr H H Snyckers  2008/09  Mr D Vos
1985/86  Dr H H Snyckers  2009/10  Mr J Louw
1986/87  Dr H H Snyckers
1987/88  Mr S P Lance
1988/89  Dr H H Snyckers
1989/90  Dr H H Snyckers
1990/91  Dr H H Snyckers
1991/92  Dr H H Snyckers
1992/93  Dr H H Snyckers
1993/94  Dr H H Snyckers
Honorary Life Members

1969  Mr B Wright
1974  Mr A L Birchley
1978  Mr N R Tuck
1979  Mr H C McGarity
      Mr S F Janet
1987  Dr R Bauling
      Mr F Wayne
1992  Mr D C Bodley
1994  Dr H H Snyckers
1998  Prof J J van Wyk
      Mr M Norris
      Mr N Dolman
1999  Dr N Kritzinger
      Mr J Niehaus
2002  Dr G Faber
      Dr J Botha
      Prof D Reekie
2008  Ms J van Oudtshoorn
      Mr P Smith
      Mr R de Chastelain
2009  Ms Maureen Kirkman
2009 PIASA Secretariat

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Chief Operating Officer Vicki Ehrich +27 11 265 2106 vicki@piasa.co.za

Personal Assistant & Betsie von Wielligh +27 11 265 2101 betsie@piasa.co.za
Office Administrator

Head: Scientific and Kirti Narsai +27 11 265 2107 kirti@piasa.co.za
Regulatory Affairs

Scientific & Regulatory Christine Schoeman +27 11 265 2102 christine@piasa.co.za
Affairs Co-ordinator

Website: www.piasa.co.za

Physical Address: Thornhill Office Park, Building No 5, 94 Bekker Street,
Vorna Valley, Midrand, 1686

Postal Address: PO Box 12123, Vorna Valley, 1686